No. 01-188

IN THE

Supreme Court of the United States

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, AND G. STEVEN ROWE, ATTORNEY GENERAL OF MAINE,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

BRIEF OF THE STATES OF MASSACHUSETTS, ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, HAWAII, INDIANA, IOWA, KENTUCKY, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, MISSISSIPPI, MISSOURI, MONTANA, NEW HAMPSHIRE, NEW MEXICO, NEW YORK, OKLAHOMA, OREGON, PENNSYLVANIA, RHODE ISLAND, SOUTH CAROLINA, SOUTH DAKOTA, TEXAS, VERMONT, WASHINGTON,WEST VIRGINIA AND COMMONWEALTH OF PUERTO RICO AS AMICI CURIAE SUPPORTING RESPONDENTS

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QUESTIONS PRESENTED

1. Whether the federal Medicaid statute, 42 U.S.C. § 1396 *et seq.*, prohibits a state from using authority under that statute to secure rebates from drug manufacturers for drugs sold to uninsured Maine residents?

2. Whether the Maine Rx statute, 22 Me. Rev. Stat. Ann. § 2681 *et seq.*, which seeks rebate payments in connection with in-state retail sales of prescription drugs to uninsured Maine residents, violates the dormant Commerce Clause because wholesale transactions in those drugs occur outside of Maine?

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INTEREST OF THE AMICI CURIAE

Amici curiae submit this brief in support of respondents Kevin Concannon, Commissioner, Maine Department of Human Services, and G. Steven Rowe, the Attorney General of Maine.

The issues posed in this case have significant implications for the States' ability to address the health care needs of their citizens, an area of traditional State concern and authority. The advent of effective pharmaceutical therapy for numerous chronic and acute medical conditions has created an opportunity to extend the lives and alleviate the suffering of millions of patients. But as the prices for these disease-sparing and often life-saving products skyrocket, and as new but also more expensive drugs are developed, a large number of persons have become unable to afford good health.[1]

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[1] Spending on prescription drugs has increased by 15% or more per year in recent years (17.1% from 2000 to 2001). The bulk of this increase reflects escalating prices and the shift to higher cost drugs. While drug spending represents about 10% of overall health care spending, it has accounted for almost a third of the increase in health care costs over the past five years. Office of the Actuary, *2000 National Health Expenditures, Chart: The Nation's Health Dollar: 2000*, http://www.hcfa.gov/stats/nhe-oact/tables/chart.htm. It is expected that prescription drug spending will continue to rise in the 10-15% range. *Express Scripts 2001 Drug Trend Report*, www.express-scripts.com.

The amici States have a strong interest in assuring their citizens effective access to necessary medical care. As prescription drugs have become an increasingly critical component of medical care and a significant and growing part of the cost of care, the amici States have developed prescription drug initiatives and/or support development of such initiatives to ensure the availability of drugs to persons who need them. The States have a strong interest in ensuring the availability of prescription drugs to their uninsured citizens, the majority of whom are low-income individuals,[2] including those ineligible for benefits under

[2] March 2002 Report of the Kaiser Family Foundation, Kaiser Commission on Medicaid and the Uninsured, "The Uninsured: A Primer, Key Facts About Americans Without Health Insurance," at 2 (almost two-thirds of the non-elderly

the Medicaid Program, 42 U.S.C. § 1396 *et seq.* ("Medicaid"), and/or elderly persons without drug coverage under the Medicare Program, 42 U.S.C. § 1395 *et seq.*[3] This interest is particularly acute given the lack of federal

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uninsured are low-income individuals or come from low-income families making less than 200% of the federal poverty level).

[3] Medicaid, operating under State statutes and funded jointly by the federal and State governments, does not require coverage for drugs; while all States have chosen to pay for prescription drugs, eligibility is limited. Original Medicare, the federal health program for the elderly, generally provides no coverage for prescription drugs in the outpatient setting. Nor is there any comprehensive federal program for people who are not eligible for Medicaid and find prescription drugs unaffordable. An estimated 23% of persons under 65 and 27% over 65 have no insurance for prescription drugs. David H. Kreling, et al., *Prescription Drug Trends: A Chartbook Update*, Menlo Park, CA: Kaiser Family Foundation (2001).

action to provide affordable prescription drugs to the uninsured.

The amici States strongly support the efforts of Maine to protect the health and welfare of its uninsured citizens through its Act to Establish Fairer Pricing for Prescription Drugs, 22 Me. Rev. Stat. Ann. § 2681 *et seq*. ("Maine Rx law" or "Maine Rx"), which seeks to extend to the uninsured pricing advantages already available to those enrolled in government programs or covered by private health plans. The disparity between retail prices–the prices paid by those least able to afford prescription drugs–and the drugs' lowest prices is significant: persons without insurance pay 123% more than the Veterans Administration Price and over 65% more than the Medicaid price.[4] Drug prices in the United States are substantially higher than

[4] William H. von Oehsen, III, *Pharmaceutical Discounts Under Federal Law: State Program Opportunities*, Public Health Institute (2001), at 9.

drug prices abroad: 50% more than prices in Canada and Great Britain, 70% more than prices in France, 90% more than prices in Italy.[5]

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[5] Alan Sager and Deborah Socolar, *A Prescription Drug Peace Treaty*, Health Reform Program, Boston University School of Public Health (2000), at 16. The drug industry has been the most profitable in the United States, as measured by median return on revenue, for each of the last ten years; during this period, the industry's profitability was one and a half times the next highest industry and nearly four times the median. *Profiting from Pain: Where Prescription Drug Dollars Go*,

Families USA Publication No. 02-015, www.familiesusa.org (2002), at 13-14.

States thus increasingly see their most vulnerable citizens face unacceptable choices–the elderly, for example, may be forced to choose between food or shelter and medication, may jeopardize their health by splitting medications to extend supply, or may even feel compelled to travel out of the country to seek access to cheaper drugs abroad. While Petitioner claims to represent the interests of Medicaid beneficiaries, its members' pricing practices contribute directly to the impoverishment that forces vulnerable persons into the Medicaid Program. The States, by contrast, have a real and strong interest in protecting both their Medicaid beneficiaries and those whose health and welfare may be endangered by diminished access to necessary medical care.

Given the severity and immediacy of the problem at the local level, the States have taken the lead in efforts to make prescription drugs more affordable and available for their citizens. Some of these efforts involve law enforcement, combating attempts by pharmaceutical companies to maintain artificially high prices by improperly seeking to extend patents and through collusive agreements with competitors not to produce generic equivalents of brand-name drugs.[6] Others, like Maine Rx,

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[6] *E.g.*, *In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d 618 (E.D. Mich. 2000) (alleged collusive agreement between brand-name and generic manufacturers to delay market entry of generic drug); *In re Buspirone Antitrust Litigation*, MDL No. 1410 (S.D.N.Y. filed Feb. 20, 2002)(alleged improper attempts by brand-name manufacturer to "evergreen" patent so as to block generic competition);*Ohio v. Bristol-Myers Squibb Co.*, No. 1:02CV01080 (D.D.C. filed June 4, 2002)(allegations that brand-name manufacturer excluded generic competition in part through enforcement of patents procured by fraud on the Patent Office).

are legislative or regulatory and are designed to serve populations whose needs are best known to the States themselves.

A number of States, including Maine, have enacted or proposed laws that provide discounted drugs to uninsured persons using negotiated manufacturer rebates. As explained by the Solicitor General, U.S. Br. 32-37, several of these programs involve formal agreements between States and the Secretary of the U.S. Department of Health and Human Services ("Secretary") to extend benefits and/or eligibility under State Medicaid Programs. These programs represent important cooperative efforts between the federal and State governments, and the amici States support the efforts of the Secretary in advancing these programs. But these are not the only programs underway at the State level,[7] and the States have a

[7] *E.g.*, some States have enacted or proposed creation of State or multi-State purchasing cooperatives to increase market leverage. Still other States have enacted or proposed laws directly regulating the activities of pharmaceutical sales representatives and industry detailers. Some States have proposed price controls or maximum prices on prescription drugs. For information concerning State initiatives, *see generally* www.ncsl.org/programs/health/drugdisc02.htm.

particularly strong interest in ensuring that their authority to act in this area is not inappropriately limited by misapplication of federal law. While there is no single solution to the problem of affordable drugs, effective responses are more likely to emerge if States retain flexibility to enact a variety of different and innovative measures and to test a number of conventional and unconventional alternatives.

The States also have a strong interest in implementing Medicaid's stated purpose: to enable States to provide medical assistance to families and individuals who cannot afford care. The Maine Rx law increases access to drugs for uninsured[8] Maine residents, including low income persons and families who make up the bulk of the uninsured in Maine and elsewhere, thus promoting Medicaid's intended purpose. It does so in a manner permitted by federal law and consistent with the welfare of existing Medicaid beneficiaries. Of great significance to the amici States, Medicaid beneficiaries will continue to receive all necessary medications, as Congress intended. There is no frustration of Medicaid's purpose. There is, however, a significant health benefit to uninsured Maine residents.

SUMMARY OF THE ARGUMENT

The Maine Rx law addresses the health and welfare of Maine citizens and is presumed valid under the Supremacy Clause. Congress has not expressly preempted the law, nor has it occupied the field. The purpose of

[8] The implementing regulations limit the Maine Rx law's benefits to persons who have "no other reimbursement option available." (J.A. 317)

Medicaid is to enable the States to provide medical assistance in a cost-effective manner to needy persons. The Maine Rx law and regulations are written and intended to ensure that Medicaid beneficiaries receive all medically necessary medications. There is no harm to Medicaid recipients, and no conflict with Medicaid. An "actual conflict", on a facial challenge, is one that will necessarily occur in all cases.

Under the Supremacy Clause, there is no requirement that a non-conflicting State law promote federal purposes. But the Maine Rx law advances what Congress said was its purpose in enacting Medicaid–to enable the States to make medical care available to those who need it and cannot afford it. The Maine law further advances what the Solicitor General and federal Centers for Medicare & Medicaid Services ("CMS") acknowledge is a Medicaid purpose: increasing the availability of drugs to financially needy individuals not eligible for Medicaid.[9] The Maine Rx law also serves an additional State purpose, to provide increased accessibility to residents who do not have insurance; it is plausible, on a facial challenge, to find that the bulk of the Maine Rx law benefits will go to low income persons and thus that the Maine law's principal purpose is also a Medicaid purpose, but nothing in the Supremacy Clause prevents a State law from advancing both federal and State purposes.

The Maine Rx law does not protect in-state commerce or affect competition in commerce. Nor does it control behavior in other States. Maine does not dictate the terms on which buyers and sellers do business outside the

[9] Letter from Dennis G. Smith, Director of CMS's Center for Medicaid and State Operations ("CMS Director")(Sept. 18, 2002), attached to U.S. Br. at 46a *et seq*.

State, and it does not set the price of any out-of-state transaction. Drug manufacturers subject to the Maine Rx law may sell drugs in any other State at any price–Maine does not know or care what the out-of-state prices are. The fact that drug manufacturers are located outside Maine is completely incidental to the purpose and effect of the Maine Rx law, which would be exactly the same if all the manufacturers were located within Maine. The Maine Rx law is not an unconstitutional regulation of interstate commerce.

ARGUMENT

I. THE MAINE Rx LAW IS NOT PREEMPTED BY MEDICAID.

Under the Supremacy Clause, Congress may preempt State laws either explicitly or by occupying a field. When State law and federal law conflict, federal law governs. But the States do not make law at the discretion of the federal government, and absent explicit or field preemption, there is no requirement that non-conflicting State laws further federal purposes, even in areas where there might otherwise be federal interests. This principle is embodied in the Tenth Amendment–all powers neither delegated to the federal government nor prohibited to the States "are reserved to the States, respectively, or to the people."

While the Federal/State balance is partly the result of historical forces whose resolution produced the constitutional model, the system also reflects the imperatives of problem-solving in the real world. Federal rules address national problems. Local rules deal with local problems; local institutions are more adept at identifying and solving such problems. Local problems can be severe,

"and state governments, in cooperation with the Federal Government, must be allowed considerable latitude in attempting their resolution." *New York State Department of Social Services v. Dublino,* 413 U.S. 405, 413 (1975).

A. The Presumption Against Preemption of State Health Care Laws.

Health care has traditionally been viewed as a local problem and State legislation related to health care as a State function. "The historic police powers of the State include the regulation of matters of health and safety." *DeBuono v. NYSA-ILA Medical and Clinical Services Fund*, 520 U.S. 806, 814 (1997). The Maine Rx law addresses health care, an area of traditional State concern.

The Court has stated many times that "where 'federal law is said to bar state action in fields of traditional state regulation...we have worked on the "assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."'" *California Division of Labor Standards Enforcement v. Dillingham Construction, NA, Inc*. 519 U.S. 316, 325 (1997) (citations omitted). The "starting presumption [is] that Congress does not intend to supplant state law." *New York State Conference of Blue Cross and Blue Shield Plans v. Travelers Ins. Co.,* 514 U.S. 645, 654 (1995).[10]

DeBuono, Dillingham, and *Travelers* are all decisions addressing ERISA, a law in which Congress

[10] State concern with health care may be contrasted with areas of peculiarly federal concern, *e.g.*, foreign affairs. *See, e.g., Hines v. Davidowitz*, 312 U.S. 52, 68 (1941). In such areas, "[a]ny concurrent state power that may exist is restricted to the narrowest of limits...."

explicitly stated an intention to preempt certain State law. The presumption must be even more cogent where Congress has not stated any intention to preempt.

B. There Is No Explicit or Field Preemption.

The Court has identified three forms of preemption under the Supremacy Clause. Preemption may be explicit: Congress "may preempt state authority by so stating in express terms." *Pacific Gas & Elec. Co. v. State Energy Resources Conservation and Development Comm'n*, 461 U.S. 190, 203 (1983). Medicaid contains no explicit statement of preemption.

Preemption may also be implied by the breadth of federal involvement; in such "field" preemption, "'the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" *Id*., *quoting from Fidelity Federal Savings & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982). In enacting Medicaid, Congress did not occupy the field. On the contrary, Congress explicitly intended the States to legislate in this area. Medicaid is "a cooperative federal/state program," U.S. Br. 2, and "every state in the nation currently operates its own Medicaid program under its own statutes." *Pharmaceutical Research & Manufacturers of America v. Meadows*, 2002 WL 31000006 (11th Cir. 2002). State Medicaid laws are diverse, and State Medicaid plans are not uniform. "States are accorded a broad measure of flexibility in tailoring the scope and coverage of their plans to meet the particular needs of their residents and their own budgetary and other circumstances." U.S. Br. 3.

C. The Supremacy Clause Does Not Require State Laws to Further Federal Aims.

Only the third form of preemption, conflict preemption, is pertinent here. Conflict preemption arises when State law "'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Pacific Gas,* 461 U.S. at 204, *quoting Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).[11]

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[11] Conflict preemption may also arise if "compliance with both federal and state regulations is a physical impossibility." *Pacific Gas,* 461 U.S. at 204, *quoting Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963). There is no claim that coexistence of the Maine Rx law and Medicaid is "physically impossible," and the Solicitor

General acknowledges that State laws that "invoke the Act's prior authorization provisions to enable non-Medicaid recipients to obtain more affordable drugs" are not prohibited by Medicaid. U.S. Br. at 30.

To strike down a conflicting law, there must be an "actual conflict" between State and federal law. The Court "has observed repeatedly that preemption is ordinarily not to be implied absent an 'actual conflict.'... The 'teaching of this Court's decisions...enjoins seeking out conflicts between state and federal regulation where none clearly exists.'" *English v. General Electric Co.*, 496 U.S. 72, 90 (1990) (citations omitted). On a facial challenge, the conflict between State and federal law must be a necessary and not simply a possible outcome: the State law must "require or authorize conduct that *necessarily* constitutes a violation" of federal law "*in all cases.*" *Rice v. Norman Williams Co.,* 458 U.S. 654, 661 (1982) (emphasis added).[12] Or, conversely, no "set of circumstances exists under which the Act would be valid." *United States v. Salerno*, 481 U.S. 739, 745 (1987). Any "possible set of ...

[12] "A high threshold must be met if a state law is to be pre-empted for conflicting with the purposes of a federal Act. Any conflict must be 'irreconcilable... The existence of hypothetical or potential conflict is insufficient to warrant the pre-emption of the state statute.'" *Gade v. National Solid Waste Mgmt. Ass'n*, 505 U.S. 88, 110 (1992), *quoting Rice v. Norman Williams Co*., 458 U.S. 654, 659 (Kennedy, J., concurring in part and concurring in judgment).

conditions not pre-empted by federal law is sufficient to rebuff [the] facial challenge...." *California Coastal Comm'n v. Granite Rock Co.*, 480 U.S. 572, 589 (1988).

The Supremacy Clause does not require non-conflicting State laws to promote federal interests. Absent actual conflict, the States are free to enact their own laws and advance their own purposes–this is indeed, a basic tenet of federalism. *Dublino,* 413 U.S. at 413. Nor does conflict preemption turn on whether a State law is "within the scope of the broad discretion that Congress afforded the states." U.S. Br. 17. In *Dublino,* on which the Solicitor General relies for this statement, the Court explicitly rejected "the contention that pre-emption is to be inferred merely from the comprehensive character" of the federal law. 413 U.S. at 415. Indeed, the Court emphasized that "'clear manifestation of (congressional) intention'... must exist before a federal statute is held 'to supersede the exercise' of state action,'" *id*. at 417 (citation omitted), and that "[t]his Court has repeatedly refused to void state statutory programs, absent congressional intent to pre-empt them." *Id*. at 413. The Court explained that "'[i]f Congress is authorized to act in a field, it should manifest its intention clearly. It will not be presumed that a federal statute was intended to supersede the exercise of the power of the state unless there is a clear manifestation of intention to do so.'" *Id.* (citation omitted). The Court did not evaluate the "discretion" Congress afforded the State, nor did it prohibit the State from advancing its own purpose–indeed, it explicitly found that "[t]o the extent that the [State] rules embody New York's attempt to promote self-reliance and civic responsibility... and to cope with the fiscal hardships enveloping many state and local governments, this Court should not lightly interfere." *Id.* at 413. Congress may "manifest its intention" to supercede

State law, but if it does not, States are free to enact laws promoting their own purposes.

D. The Maine Rx Law Does Not Conflict with Medicaid

1. The Purpose of Medicaid. Congress enacted the Medicaid program to enable "each State, as far as practicable under the conditions in such State, to furnish...medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396. The States have wide flexibility in designing "medical assistance" provided under the State plans. *See, e.g.*, *Alexander v. Choate,* 469 U.S. 287 (l985). Medicaid does not require the States to pay for prescription drugs. 42 U.S.C. § 1396d(a)(12). The purpose of Medicaid is not to provide all possible benefits to eligible recipients, but to provide "medical assistance."

Congress expressly permitted States choosing to pay for Medicaid prescription drugs to "subject to prior authorization any covered outpatient drug." 42 U.S.C. § 1396r-8(d).[13] There is no limitation in Medicaid on the number or identity of drugs subject to prior authorization.

[13] It also permitted States to establish formularies, lists of drugs approved for inclusion in (but not necessarily payment by) a State's Medicaid Program, 42 U.S.C. § 1396r-8(d)(4)(C). The formulary provision, adopted in 1993, provides that any excluded drugs must be subjected to a prior authorization program. 42 U.S.C. § 1396r-8(d)(4)(D).

Nor is there any limitation on a State's motive or rationale in subjecting a drug to prior authorization.[14]

[14] The only restrictions Congress placed on prior authorization were intended to ensure that delay would not affect the ability of patients to obtain medically necessary drugs. This was accomplished by requiring prior authorization programs to "provide[] response by telephone or other telecommunication device within 24 hours of a request for prior authorization" and "provide[] for the dispensing of at least a 72-hour supply of a covered outpatient prescription drug in an emergency situation." 42 U.S.C. § 1396r-8(d)(1)(A), (d)(5).

Thus, it is not Medicaid's purpose to supply all prescription drugs or any specific drugs. It is not the purpose of Medicaid to provide recipients with drugs that are "paid for by Medicaid without reservation." Pet. Br. 16.[15] Medicaid's purpose is to provide "medical assistance"–to "ensure access...to prescription drugs where medically necessary." H.R. Rep. No. 101-881 (1990), at 98; Pet. Br. 23. Providing medically necessary drugs is the

[15] Nor is it the purpose of Medicaid to provide so-called "first choice" drugs. (J.A. 150). Indeed, such drugs may not be the safest and most effective in all situations. *Id*. Further, by choosing the more expensive of two equally effective drugs, a physician's "first choice" may harm the Medicaid program by reducing its ability to purchase other needed drugs.

"best interest" of recipients required by Medicaid. 42 U.S.C. § 1396a(a)(19).[16]

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[16] The reference in Medicaid to "consisten[cy] with simplicity of administration and the best interests of recipients" does not create an entitlement to "first choice" or extensively promoted drugs; given the prior authorization and formulary provisions and Congress's stated intention to "ensure access...to prescription drugs when medically necessary," H.R. Rep. No. 101-881 at 98, State laws that provide access to medically necessary drugs–and limit access to other drugs–are consistent with "simplicity of administration and the best interests of recipients."

OBRA 1990 made clear that the States may "require prior authorization with respect to any of the prescription drugs which they elect to cover" and "the bill would not affect any authority States have under current law to impose prior authorization controls on prescription drugs." 42 U.S.C. § 1396r-8(d); H.R. Rep. No. 101-881 at 95, 98.[17] Thus, while Congress "requir[ed] states to cover all drugs of participating manufacturers," Pet. Br. 23–and, of course, the Maine Rx law does not affect the coverage or participation in Medicaid of any drug–it did not limit the States' ability to "cover" any drug subject to prior authorization for any reason. OBRA 1990 created not a "delicate balance" of entitlements and limitations, Pet. Br. 23, but a condition precedent to participation of any drug in Medicaid–provision of a rebate. There is no entitlement to sell drugs free from prior authorization, and there is no limit on the States' ability to subject a participating drug to prior authorization.

2. The Maine Rx Law. The Maine Rx law "was enacted because of the Maine Legislature's concern that many Maine citizens who were not Medicaid recipients could not afford necessary prescription drugs." 249 F.3d 66, 71. The program is open to all State residents, *id.*; the implementing rules limit the discounts to individuals who do not have "other reimbursement option[s] available." (J.A. 317)

The regulations provide that drugs from manufacturers not providing rebates to Maine Rx will be subject to prior authorization only when clinically appropriate, and that Medicaid patients "shall be assured

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[17] Before 1990 the States had "routinely required prior authorization for prescription or dispensing of drugs." U.S. Br. 19.

access to all medically necessary outpatient drugs." (J.A. 320) An advisory board comprised of physicians and pharmacists

> will make the final determination of the clinical appropriateness of any recommendation that a prior authorization requirement be imposed with respect to a particular prescription drug manufactured by a manufacturer which has not entered into a Maine Rx Rebate Agreement. In making its determination of whether or not a prior authorization requirement is clinically appropriate, the DUR Committee shall be guided by the law of Medicaid, and particularly the principle that Medicaid recipients shall be assured access to all medically necessary prescription drugs.

(J.A. 167) *See Dublino,* 413 U.S. at 421 (the State "has attempted to operate the [State] rules in such a manner as to avoid friction" with federal law). "[D]etermination of whether a particular drug should be subjected to prior authorization requirement will be based firmly upon considerations of medical necessity." (J.A. 149)

While Petitioner does not explicitly accuse the Maine Rx law of impairing the health of Medicaid recipients, its brief is replete with references to "[h]olding Medicaid patients hostage", "threaten[ing] Congress' intended beneficiaries", "risks with Medicaid patients health", "ransom", and "burden", Pet. Br. 2, 13, 14, *passim,* references that suggest harm to individuals that, if the Maine law is implemented as written and intended, will not occur. No beneficiary will be injured. No one will be denied access to medically necessary drugs.

3. There is No "Actual Conflict" Between the Maine Rx Law and Medicaid. Medicaid's purpose is to

enable the States to provide "medical assistance" in a cost-effective manner to those who cannot afford necessary medical care. Under Maine Rx, the State of Maine provides medical assistance to uninsured persons and assures Medicaid recipients "access to all medically necessary prescription drugs." (J.A. 167) There is no conflict with Medicaid's purpose.

When a drug is unique or medically necessary, the beneficiary will receive the drug, and Petitioner's relevant member will receive payment. (J.A. 149) When there are a number of identical or medically comparable drugs, however, subjecting one to prior authorization may result in disappointing sales for its manufacturer (it may also increase sales for a competitor). But Medicaid does not guarantee sales of a particular manufacturer's drug. It does not guarantee that a drug manufacturer will be able to sell its drug to the State without prior authorization. Nor is it the purpose of Medicaid to provide "unrestricted" access to drugs. So long as the beneficiary receives medically appropriate drugs, Medicaid's purpose is accomplished.

To find preemption on a facial challenge, the Maine Rx law must "necessarily" conflict with Medicaid "in all cases." *Rice v. Norman Williams Co.,* 458 U.S. at 661. Petitioner argues that there is a "serious risk" that persons confronted with prior authorization may go without needed drugs. Pet. Br. 6. But this is not a *necessary* outcome. And it is not an intended outcome–the law and the "regulations as written"[18] state that prior authorization will be consistent with therapeutic requirements, and Medicaid recipients will always receive medically necessary drugs. Since it is both intended and plausible that the Maine Rx

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[18] *See Department of Taxation and Finance of New York v. Milhelm Attea Bros., Inc.,* 512 U.S. 61, 69 (1994).

law will not affect the ability of Medicaid recipients to obtain medically necessary drugs–and since there is plainly a "possible set of conditions" under which the Maine Rx law does not conflict with Medicaid–there is no "actual conflict" and no preemption under the Supremacy Clause. *See California Coastal Comm'n v. Granite Rock Co.,* 480 U.S. at 509.

E. The Maine Rx Law Serves a Federal Purpose.

Even though conflict preemption does not require State law to further a federal purpose, the Maine Rx Law does further a Medicaid purpose. The purpose of Medicaid is broad–to enable States to provide medical assistance to "families with dependent children and...aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396. The Maine Rx law furthers this purpose by using Medicaid prior authorization to enable Maine to provide medical assistance to uninsured families and individuals. The Maine Rx law is not addressed to bridge-building or job-training,[19] but to the

[19] The Solicitor General refers to the "leverag[ing of] its Medicaid program to force a drug manufacturer to fund the State's transportation or education systems," U.S. Br. 25, and Petitioner to subsidization of "food stamps, public housing job training projects, and any number of other public projects that would boost Maine residents' income and thereby potentially keep them off Medicaid." Pet. Br. 25-26. These are entirely hypothetical concerns, since the Maine Rx law does none of these things. But if there is no preemption under the Supremacy Clause, "it is for Congress to rethink the division of regulatory authority in light of its possible exercise by the states to undercut a federal objective. The courts should not assume the role which our system assigns to Congress." *Pacific Gas,* 461 U.S. at 223.

health care needs of Maine citizens who "are admitted to or treated at hospitals each year because they cannot afford the drugs prescribed for them," who "must enter expensive institutional care settings because they cannot afford their necessary prescription drugs" and who "are threatened by the possibility that when they need medically necessary prescription drugs most they may be unable to afford their doctor's recommended treatment." Me. Rev. Stat. Ann. c. 603 § A-5(1). The expressly stated purposes of Medicaid and of the Maine Rx law are "common purposes", *Dublino,* 413 U.S. at 421: to ensure that all persons can afford to receive the health care they need.

Limiting Medicaid's purpose to something narrower than Congress's stated purpose is improper.[20] But even viewed narrowly, the Maine Rx law serves a Medicaid purpose. As the court below found, "by making prescription drugs more accessible to the uninsured, Maine may reduce Medicaid expenditures." 249 F.3d at 76. Specifically, "[w]hen people whose incomes fall outside Medicaid eligibility are unable to purchase necessary medication, their conditions may worsen, driving them further into poverty and into the Medicaid program, requiring more expensive treatment that could have been avoided had earlier intervention been possible." *Id*. The CMS Director has similarly stated that "making available to

[20] Conflict preemption analysis is plainly sensitive to the determined federal "purpose". Petitioner and the Solicitor General ask the Court to find a Medicaid purpose considerably narrower than Congress's expressed purpose; given the breadth and clarity of Congress's language, it is ironic that in the Solicitor General's view, providing affordable health care to uninsured citizens is not a Medicaid purpose, but keeping persons out of the Medicaid program is a legitimate Medicaid purpose. *See, e.g.*, U.S. Br. 35.

financially needy [but not Medicaid-eligible] individuals medically necessary prescription drugs, thereby improving their health status and making it less likely that they will become Medicaid eligible," is a Medicaid purpose.[21] In his brief, the Solicitor General agrees that "[a] prescription drug discount for non-Medicaid populations, made possible by encouraging manufacturers to give rebates, could significantly decease the chance that such [lower income persons not meeting Medicaid's eligibility requirements]

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[21] Letter of Dennis G. Smith, *supra* note 9. In the Director's view, a State law that uses prior authorization to leverage discounts for non-Medicaid persons is a "material change" in State law "and we would therefore expect a State to submit a plan amendment to CMS for review." The Director is careful not to state, however, that Medicaid requires such submission. The fact that a State may apply to CMS for approval, moreover, does not mean that in the absence of such application for approval, State law is preempted. Petitioner has not challenged the Maine Rx law on the ground that no submission to CMS was made–that issue is not before the Court, U.S. Br. 39, n.11–nor would it have standing to do so.

will become Medicaid-eligible as either categorically or medically needy individuals, and thereby drain the State's scarce Medicaid resources." U.S. Br. 39. Thus, States may "make drugs more affordable to certain non-Medicaid populations by subjecting drugs to prior authorization under Medicaid in order to encourage drug manufacturers to agree to offer prescription drug discounts for those populations." *Id.* at 37-38 (footnote omitted).

There is no real dispute that low-income persons will benefit under the Maine Rx law; the benefits such persons will receive from the Maine program are precisely the same as the benefits they would have received had Maine Rx been limited to such persons. Low income persons represent nearly two-thirds of the nonelderly uninsured, *see* note 2, *supra*; on a facial challenge, it is reasonable to find that the bulk of the Maine Rx benefits will go to low income persons–those with the least means and the greatest need for drugs–and that the primary purpose of the law is also a Medicaid purpose.

In his brief, the Solicitor General acknowledges that Medicaid does not preempt State laws employing Medicaid prior authorization to benefit an appropriate non-Medicaid population, U.S. Br. 30, 39, but argues that the Maine Rx law benefits a non-Medicaid group that is too broad.[22] In his view, the Maine Rx law is problematic not because it

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[22] The Solicitor General also argues that the Maine Rx law's statement or purpose does not "reveal any Medicaid objective." Of course, "when considering the purpose of a challenged statute, this Court is not bound by '[t]he name, description or characterization given it by the legislature or the courts of the State,' but will determine for itself the practical impact of the law." *Hughes v. Oklahoma*, 441 U.S. 322, 336 (1979) (citation omitted).

leverages prior authorization to obtain rebates for non-Medicaid persons–he agrees this is not prohibited by Medicaid, *id.* at 37-39–but because it benefits both persons who may become eligible for Medicaid and others who may not, thus furthering both federal and State purposes.

This is a fine distinction for a constitutional standard. It is not a distinction Congress made when it enacted or amended Medicaid: there is no "clear manifestation of intention," *Dublino*, 413 U.S. at 417, to prevent the States from using prior authorization and rebates to benefit uninsured persons. And it is difficult to see where a requirement that State law *exclusively* further a federal purpose comes from. Conflict preemption asks whether State law is an "obstacle" to a federal purpose. *Pacific Gas.* The Maine Rx law will benefit low-income persons and will benefit Medicaid in precisely the manner the Solicitor General and the CMS Director deem an appropriate Medicaid purpose: "[a] prescription drug discount for non-Medicaid populations, made possible by encouraging manufacturers to give rebates, could significantly decrease the chance that such persons will become Medicaid-eligible...and thereby drain the State's scarce Medicaid resources." U.S. Br. 39. If State law furthers a federal purpose, it is not an obstacle. There is no preemption.

II. THE MAINE Rx LAW DOES NOT VIOLATE THE DORMANT COMMERCE CLAUSE.

The Maine Rx rebates result from the sale, in Maine, of prescription drugs. While most manufacturers sell their drugs to out-of-state middlemen before the drugs are sold in Maine, the Maine Rx law does not regulate or control the prices of those transactions, and the rebates are not based on the prices of those transactions. If the Maine

Rx law is barred by the Commerce Clause, "a wide variety of permissible state regulations that may affect the conduct of out-of-state manufacturers," U.S. Cert. Br. 17, including products liability laws, *id.*, and laws regulating insurance and other goods and services sold by out-of-state entities, might also be threatened. For this reason, the Court has found that "the States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected." *Maine v. Taylor***,** 477 U. S. 131, 138 (1986).

In the Court's more recent decisions, the dormant Commerce Clause has been employed to prohibit two forms of State conduct.[23] First, a State law may not favor or protect in-state over out-of-state commerce. Second, a State law may not control prices or behavior in other States.[24] A law that "has only indirect effects on interstate commerce and regulates evenhandedly," on the other hand,

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[23] In older (primarily common carrier) cases, the dormant Commerce Clause was also invoked to preclude State legislation in areas in which national uniformity was required, at least in the absence of legitimate State interests. *See, e.g., Southern Pac. Co. v. Arizona,* 325 U. S. 761 (1945).

[24] Decisions striking down laws found to be protective include *West Lynn Creamery, Inc. v. Healy,* 512 U. S. 186 (1994), *New Energy Co. of Indiana v. Limbach,* 486 U. S. 269 (1988), and *Bacchus Imports, Ltd. v. Dias,* 468 U. S. 263 (1984). Decisions striking down "extraterritorial" laws include *Healy v. Beer Inst., Inc.,* 491 U. S. 324 (1989), and *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U. S. 573 (1986). Some laws are both protective and extraterritorial. *See, e. g., Baldwin v. G. A. F. Seelig., Inc.,* 294 U. S. 511 (1935).

will not be disturbed so long as "the State's interest is legitimate" and the burden on interstate commerce does not "clearly exceed [] the local benefits." *Pike v. Bruce Church, Inc.,* 397 U.S. 137, 142 (1970).

The Maine Rx law does not protect in-state commerce or control behavior in other States and thus is valid under the Commerce Clause.

A. The Maine Rx Law Is Not Improperly Protective.

The "'negative' aspect of the Commerce Clause prohibits economic protectionism–that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors." *New Energy Co. of Indiana v. Limbach,* 486 U.S. at 273. It bars laws when "the avowed purpose of the obstruction, as well as its necessary tendency, is to suppress or mitigate the consequences of competition between the states." *Baldwin,* 294 U.S. at 522. In *West Lynn Creamery,* the Court likened such protection to a State tariff–"[t]he paradigmatic example of a law discriminating against interstate commerce is the protective tariff or customs duty." 512 U.S. at 193. The tariff mechanism "handicap[s] out-of-state competitors, thus artificially encouraging in-state production even when the same goods could be produced at lower costs in other states." *Id.*

The Maine Rx Law is not a protective law, and it does not suppress competition. While Petitioner claims "[t]he Maine Rx rebate has an effect similar to that of a duty imposed at the state's border," Pet. Br. 29, the Maine rebate is not intended to and does not protect in-state producers. It does not establish an "economic barrier" or "rampart", *Baldwin*, 294 U.S. at 527, securing domestic competitors from out-of-state competition. The laws in *West Lynn Creamery, Baldwin,* and other dormant

Commerce Clause cases would not have existed had the producers all been in-state producers–protection of in-state from out-of-state producers was the necessary purpose and desired effect of these laws. But if all drug manufacturers were located in Maine, the Maine Rx law would still serve its intended purpose and have its intended effect of increasing access to prescription drugs. It does not injure commerce among the states.

Petitioner seeks to bring the Maine Rx law within the ambit of *West Lynn Creamery* by referring to Maine's prescription drug users as "in-state economic interests" benefitted by the Maine Rx law. Pet. Br. 36, 37. But the law in *West Lynn Creamery* was not struck down simply because a benefit was conferred on in-state persons. The Commerce Clause concern in *West Lynn Creamery* was that the law's "avowed purpose and its undisputed effect are to enable higher cost Massachusetts farmers to compete with lower cost dairy farmers in other States." 512 U.S. at 194. "The pricing order thus allows Massachusetts dairy farmers who produce at higher cost to sell at or below the price charged by lower cost out-of-state producers," *id*. at 194-95, providing "domestic producers an additional tool with which to shore up their competitive position." *Id.* at 197. "[T]he purpose and effect of the pricing order are to divert market share to Massachusetts dairy farmers. This diversion necessarily injures the dairy farmers in neighboring States." *Id.* at 204. The decision in *West Lynn Creamery* was based on impermissible economic protectionism–the discriminatory advantaging of in-state over out-of-state producers.[25]

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[25] Petitioner concedes that *West Lynn Creamery* involved protectionism, but argues that this "feature was neither necessary nor dispositive in *West Lynn,*" and points to the Court's "reject[ion of] Massachusetts' argument that its scheme was not

discriminatory because the milk dealers who paid the tax did not compete with the dairy farmers who reaped the subsidy." Pet. Br. 38. The Court rejected this argument not because it found protectionism unnecessary, but because protectionism can be implemented in a variety of ways, including a tax on a third party, and competition can be constrained "at any point." 512 U.S. at 202.

The "discrimination" addressed by the dormant Commerce Clause is "discriminat[ion] against interstate commerce." *Bacchus Imports, Ltd v. Dias,* 468 U.S. at 268. In *Bacchus,* on which *West Lynn Creamery* relied, the Court stated a "cardinal of rule of Commerce Clause jurisprudence... that '[n]o State, consistent with the Commerce Clause, may "impose a tax which discriminates against interstate commerce... by providing *a direct commercial advantage to local business.*"'" *Id.* (citations omitted; emphasis added). Commerce Clause "discriminatory effect" is predicated on competition: "as long as there is some competition between the locally produced exempt products and non-exempt products from outside the State, there is a discriminatory effect." *Id.* at 271. The law in *Bacchus* "constitute[d] 'economic protectionism' in every sense of the phrase" and "violated the Commerce Clause because it had both the purpose and effect of discriminating in favor of local products." *Id*. at 273. "It has long been the law that States may not '*build up* [their] *domestic commerce* by means of unequal and oppressive burdens upon *the industry and business of other States.*'" *Id.* at 272 (citation omitted; emphasis added). Petitioner's reference to persons needing drugs as "in-state economic interests" is inapposite for purposes of Commerce Clause analysis–these persons are not engaged in commerce, and the reduction in drug prices is not designed to and does not build up domestic commerce at the expense of the industry and business of other States.

The Maine Rx law does not protect in-state commerce. It has no discriminatory purpose or effect and is not barred by the Commerce Clause.

B. The Maine Rx Law Is Not an Extraterritorial Law.

1. Maine Does Not Regulate Transactions That Take Place Outside Its Borders. In determining whether a State law impermissibly regulates transactions outside its borders, "[t]he critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State." *Healy,* 491 U.S. at 336.

The Maine Rx law does not control any out-of-state transaction. Drug manufacturers subject to the Maine Rx law may transact business anywhere they like, with any entity they like and on any terms they like. Maine does not "dictate the terms on which buyers and sellers do business outside the state," nor does it "regulate the terms of transactions in other states." Pet. Br. 27, 28.

If manufacturers agree to pay a rebate, there is no requirement that they alter their out-of-state conduct in any way. If they do not agree, there is similarly no effect on out-of-state conduct. In either case, it does not matter that the "manufacturers and their customers (independent wholesalers and distributors) are located outside Maine," Pet. Br. 29, because the Maine Rx law does not control the out-of-state conduct of any of these entities. *See* U.S. Cert Br.17.

In *Baldwin, Brown-Forman* and *Healy,* relied on by Petitioner, Pet. Br. 28, the State laws set or determined the prices of transactions in other States. The "'practical effect' of the law[s was] to control...prices in other states." *Brown-Forman,* 476 U.S. at 583. The Maine Rx law, by contrast, does not restrict drug manufacturers' ability to price their products in any State. It does not control wholesale prices or place a ceiling on out-of-state prices. Transactions in other States are not affected by or germane to the Maine Rx law–Maine is neither aware of nor concerned with out-of-state sales. Manufacturers are not required to comply with a Maine regulation in order to sell

their products in another State. Maine does not control commerce in other States.

2. Maine Rx Rebates Are Not Impermissibly Tied to Out-of-State Prices. The Maine Rx law directs the Commissioner to "negotiate the amount of the rebate" with manufacturers and in the negotiation to "take into consideration the rebate calculated under the Medicaid Rebate Program." 22 Me.Rev.Stat.Ann § 2681(4). In the negotiation, the Commissioner is to use "best efforts" to obtain a rebate equal to or greater than the Medicaid rebate amount. *Id*.

The State laws in *Brown-Forman* and *Healy* required sellers to set prices within the State that were no higher than the lowest price charged anywhere else in the United States (*Brown-Forman*) or in neighboring States (*Healy*). Once the seller affirmed that it was selling at the lowest price, it could not then lower its price in other States without violating the first State's law (or, in *Brown-Forman,* obtaining the first State's approval), and thus the first State's price effectively set a floor on the prices in other States. It was this "control" of the other States' prices that made the laws' referential prices offensive. *Brown-Forman,* 476 U.S. at 583.

Under the Maine Rx law, rebates are negotiated. When a rebate is provided, there is no requirement that the negotiated rebate be lower than or higher than or the same as a price charged in any other State. The suggestion in Petitioner's brief that lowering its "federal price will directly trigger a larger Maine Rx rebate," Pet. Br. 34, is inconsistent with the Maine Rx law. There is no "direct" relation between the Maine Rx rebate and any other price.

The issue in *Brown-Forman* and *Healy,* moreover, was not simply that a State law referred to a price; the laws tied in-state retail prices to retail prices *in other States. See, e.g., Healy,* 491 U.S. at 338. A State law that referred

to a federal price–even one that mandated the matching of a federal price–could not have this effect; a manufacturer selling to the federal government would be required to charge the same price in the State whose law referred to the federal price, but there would be no effect on prices or commerce in other States. Similarly, if the Maine Rx law required the Maine Rx rebate to match exactly the federal Medicaid rebate in all cases (there is no such requirement), there would be no impact on the price in any other State. The manufacturer would pay the Medicaid rebate in Maine and would be free to charge whatever price it wanted in other States.

Even Petitioner concedes that "[t]he key offensive element of the price affirmation statutes in *Brown-Forman* and *Healy* was their effect on consumers and the competitive market in other states. The sellers in New York and Connecticut were prevented from setting prices in other states based solely on the competitive conditions prevailing there." Pet. Br. 33. The Maine Rx law does not prevent manufacturers from setting their own retail or wholesale prices in other States or selling their drugs for prices lower than the Maine price in other States. Nor does it prevent them from offering a lower price to the federal government.[26] If other states "follow Maine's lead and link in-state rebate demands to the federal Medicaid rebate level," such States would have "best efforts" negotiated rebate provisions like the Maine Rx law, and there would be no effect on prices in other States. There would be no

[26] Even a mandatory rebate provision that required manufacturers to match exactly the Medicaid rebate would probably not affect the manufacturer's ability to offer a lower price to the federal government, but this is not in any event a Commerce Clause problem.

"competing and interlocking local economic regulation that the Commerce Clause was meant to preclude." *Healy,* 491 U.S. at 337. Manufacturers would be free to negotiate (or refuse to negotiate) appropriate rebates, which might or might not be the same as the Medicaid rebate or each other. There would be no inconsistent obligations and no "price gridlock". *Id.* at 340.

The Maine Rx law does not set or limit prices in other States, and it is not barred by the Commerce Clause.

C. The Maine Rx Law Must Be Sustained Under the Pike Test

The Maine Rx law is not discriminatory in purpose or effect, and the provision of prescription drugs to Maine citizens is an important local public interest. *See, e.g., New Energy Co. of Indiana v. Limbach,* 486 U.S. at 279 ("[c]ertainly the protection of health is a legitimate state goal"). The Maine Rx law is a legitimate State regulation of health and welfare, and it is not barred by the Commerce Clause. *Pike* v. *Bruce Church, Inc.,* 397 U.S. at 142.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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